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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
| 09/281,760 | 03/30/99 | LAWTON | R 241708 |
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| IDEXX | | | EWOLDT, G |
| C/O HOWREY SIMON ARNOLD & WHILE LLP - SD | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

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|-------------------------------|-------------------------------|
| Application No. 09/281,760 | Applicant(s) Lawton et al. |
| Examiner G. R. Ewoldt | Art Unit 1644 |

-- THE MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Mar 2, 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-115 is/are pending in the application.

4a) Of the above, claim(s) 3-5, 12-14, 18-20, 24-26, 31-33, 38-40, and 44-11 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1, 2, 6-11, 15-17, 21-23, 27-30, 34-37, and 41-43 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 21

20) Other: _____

DETAILED ACTION

1. Claims 1-2, 6-11, 15-17, 21-23, 27-30, 34-37, and 41-43 are being acted upon.

2. In view of Applicant's amendment and response, and the declaration of Inventor Gregory Francoeur, filed 3/02/01, only the following rejections remain.

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 6-11, 15-17, 21, 23, 27-30, 34-37, and 43 stand rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in Paper No. 16, mailed 10/24/00.

Applicant's arguments, filed 3/02/01, have been fully considered but have not been found persuasive. Applicant argues that the data in the specification adequately support the invention, particularly the use of phage display technology. Applicant argues that the specification discloses that the 8H.8 antibody binds a number of peptides fitting the claimed L-X-X-Y-R motif. Applicant continues with an argument that the 8H.8 antibody binds the amino acid motifs of SEQ ID NOS:9 and 10.

Applicant's arguments center on the disclosure of the various peptides that might be bound by a single monoclonal antibody (8H.8). The instant claims, however, are drawn to various "binding proteins", i.e., any antibodies that might bind the various sequences encompassed by the claimed motif. The single disclosed embodiment, the monoclonal antibody 8H.8, is insufficient support for the generic claims. Applicant's arguments regarding the binding properties of the 8H.8 antibody are somewhat irrelevant in that they can only further define the properties of the single embodiment and can not address the rejection of the claimed genus. Also note that Applicant's argument's regarding the ability of the 8H.8 antibody to bind SEQ ID NOS:9 and 10 appear nonsensical in that said sequences do not comprise the L-X-X-Y-R motif.

Applicant has further submitted three references in support of the claimed invention. Said references, however provide insufficient support for the claimed binding proteins. The Dayhoff et al. and Doolittle references simply describe the concepts of protein conservation and the relationships/similarities of various amino acids. Said references are silent as to binding protein/ligand interactions. The Stanfield et al. reference teaches generic binding protein/ligand concepts but is silent as to the binding protein/ligand motifs of the instant claims. It is noted, however, that the reference teaches the "exquisitely specific recognition of antigen by [an] antibody" and that "each antibody is highly specific for its own peptide antigen sequence," which would appear to teach away from the claimed invention.

The declaration of Inventor Gregory Francoeur under 37 CFR 1.132, filed 3/02/01, is insufficient to overcome the rejection of claims 6-11, 15-17, 21, 23, 27-30, 34-37, and 43 based upon the first paragraph of 35 U.S.C. 112 as set forth in the last Office action for the following reasons:

The Inventor asserts that "The claimed invention is directed towards a conserved peptide motif which binds to the specific binding protein disclosed in the specification." Said assertion is incorrect - the claimed invention is actually directed towards a genus of binding proteins which bind a conserved peptide motif. Thus the arguments of the declaration, much like the arguments of Applicant's remarks, do not speak to the full scope of the claimed invention, and thus can not support said invention. Also, note that the data disclosed in the declaration was again generated with the single embodiment of the specification, i.e., the 8H.8 monoclonal antibody. Thus, said data can only support the single disclosed embodiment and not the binding proteins of the generic claims. Further note that while the Declarant asserts himself to be "skilled in the art relating to the invention," Declarant has neither a significant educational background nor any publications in the art.

5. Claims 1-2, 6-10, 17, 23, 27-30, 34-37, and 43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in Paper No. 16, mailed 10/24/00.

Applicant's arguments, filed 3/02/01, have been fully considered but have not been found persuasive. Applicant argues that "specific binding proteins (molecules)" are adequately described on page 17 of the specification. However, the only definition disclosed on said page is a circular definition, i.e., a binding molecule is a molecule that binds. Said definition is an insufficient description of the claimed invention.

6. Claims 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in Paper No. 16, mailed 10/24/00.

Applicant's arguments, filed 3/02/01, have been fully considered but have not been found persuasive. Applicant argues that the disclosure of the antigen used to generate the 8H.8 monoclonal antibody is sufficient to enable the production of said antibody without undue experimentation. The Examiner disagrees.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 17, 23, 30, 37 and 41 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) In claims 17, 23, 30, 37, and 43, the recitation of the term "recombinant binding molecule" renders the claims ambiguous and indefinite. Said term has no specific well-known meaning within the art and has not been defined in the specification.

B) In claim 41, the recitation of the laboratory designation "8H.8" renders the claims ambiguous and indefinite. Applicant is advised to recite the ATCC designations for the hybridoma and antibody it produces.

Applicant's arguments, filed 3/02/01, have been fully considered but have not been found persuasive. Regarding A, Applicant reiterates the circular, i.e., a binding molecule is a molecule that binds, definition disclosed in the specification. It is the Examiner's position that said definition is vague and indefinite. Regarding B, a rejection under 112, second paragraph

is proper if the Examiner has determined that the invention has not been adequately described, i.e., Applicant has not set forth what Applicant regards as his invention. In the instant case, laboratory designations can not be considered a universal designation; said designations are subject to change at any time. Additionally, a laboratory designation can be variable from laboratory to laboratory. Therefore, Applicant has not set forth what Applicant regards as his invention, see M.P.E.P. 2411.01.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims are 1 and 2 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 95/31728 (1995), for the reasons of record set forth in Paper No. 16, mailed 10/24/00.

Applicant has presented no arguments traversing this rejection of Claims 1 and 2.

11. Claims are 1 and 2 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,321,123 (1994), for the reasons of record set forth in Paper No. 16, mailed 10/24/00.

Applicant has presented no arguments traversing this rejection of Claims 1 and 2.

12. Applicant is advised that should the claims be amended to recite the binding proteins of the claims before the amendment filed 3/02/01, the art rejections previously made of said claims would be reinstated.

13. The following are New Grounds for Rejection necessitated by Applicant's amendment, filed 3/02/01.

14. Claims 1, 6, 27, and 34, are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) "A specific binding protein which specifically binds to native canine free or B cell-bound IgE,"

B) "... a leucine positioned two amino acids toward the amino terminus from a tyrosine arginine-pair."

Applicant's amendment, filed 3/02/01, fails to assert that no new matter has been added, and no specific support for the newly claimed subgenus has been found in the specification. Note that the narrowing of a claim to an unsupported subgenus or species (as in Claim 1) may also constitute new matter, see M.P.E.P. 2163.05.

15. No claim is allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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May 16, 2000

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